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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/759,832	01/15/2004	Dov Michaeli	1102865-0059 CIP	8298
7470	7590	01/25/2006	EXAMINER	
WHITE & CASE LLP PATENT DEPARTMENT 1155 AVENUE OF THE AMERICAS NEW YORK, NY 10036			KIM, YUNSOO	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 01/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/759,832	Applicant(s) MICHAELI ET AL.	
	Examiner Yunsoo Kim	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 13,15-17,34-38,40 and 49-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12,14,18-33,39 and 41-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/6/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-51 are pending.
2. Applicants' election without traverse of Group I, claims 1-33, 39, 41-48 drawn to a liposomal composition read upon elected species of SEQ ID NO:7 as an immunomimic peptide, SEQ ID NO:10 as a spacer and phosphatidyl choline as a phospholipid in the reply filed 11/10/05 is acknowledged.

Accordingly, claims 13, 15-17, 34-38, 40 and 49-51 are withdrawn from further consideration by the examiner 37 CFR 1.142 (b) as being drawn to a nonelected invention/species.

Claims 1-12, 14, 18-33, 39 and 41-48 read on elected species of SEQ ID NO:7 as an immunomimic peptide, SEQ ID NO:10 as a spacer and phosphatidyl choline as a phospholipid are under consideration.

3. Sequence Compliance: The instant application appears to be in sequence compliance for patent application containing amino acid sequence disclosures.
4. Applicants' IDS filed on 7/6/04 has been considered.
5. The following is a quotation of the second paragraph of 35 U.S.C.112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claims 28-31, 43 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "immunomodulatory substance" in claims 28-31 is indefinite because it is ambiguous as to the direction (positive or negative) or degree of said modulating.

The term "substantially" in claims 43 and 45 is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

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7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1, 9, 12, 14, 26 and 27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a liposomal composition comprising an amino acid sequence consisting of SEQ ID NO:7, does not reasonably provide enablement for a liposomal composition comprising of any immunomimic peptide or fragment thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use of the invention commensurate in scope with these claims.

The specification disclosure does not enable one skilled in the art to practice the invention without any undue amount of experimentation.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed.Cir.1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of the skilled in the art to practice the claimed invention.

The phrases “immunomimic peptide” in claim 9 and “fragment thereof” in claim 12 have not provided sufficient biochemical information that distinctly identifies a liposomal composition other than the immunomimic peptide selected from the group consisting of gastrin G-17, gastrin G-34, GnRH and hCG. The specification fails to provide sufficient guidance and direction as to how the skilled artisan can make such compositions, commensurate in scope with the claimed invention.

Ngo *et al* teach that the amino acid positions within the polypeptide/protein that can tolerate change such as conservative substitution or no substitution, addition or deletion which are critical to maintain the protein's structure will require guidance (see Ngo et al., 1994, The Protein Folding Problem and Tertiary Structure Prediction, pp. 492-495 in particular).

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In view of the quantity of experimentation necessary, the limited working example, the unpredictability of the art, the lack of sufficient guidance in the specification, and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

9. Claims 1, 9, 12, 14, 26 and 27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is insufficient written description for any liposomal composition comprising of any immunomimic peptide fragment because any fragment reads on any dipeptide or longer and protein of different chemical or physical properties are not set forth in the specification as filed, commensurate in scope with the claimed invention.

Therefore, Applicants do not possess of scope of claimed invention. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of use.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-7, 10, 11, 18-24, 28-30, 32, 41 and 43-48 are rejected under 35 U.S.C. 102(b) as being anticipated by the U.S. Pat. No. 5,919,480 (IDS reference).

The '480 patent teaches an injectable multilamellar liposomal composition comprising water soluble agent (col. 6, lines 25-51), protein to lipid molar ratio is 100-1000 (col. 7, lines 8-10) and vesicle forming composition comprising dimyristoyl phosphatidyl choline (DMPC, col. 5, lines 40-55).

The '480 patent further teaches the encapsulation efficiency is 85% (Example 6, col. 14-15 overlapping paragraph), use of cytokine as immunostimulating agent (Examples 5-9), dose of 66 ug (col. 13, example 1), sterilization (col. 7, lines 5-7), various routes of administration including intramuscular, subcutaneous, and intradermal (col. 7, lines 38-49) and lipid comprising polar headgroup (i.e. ester) and hydrophobic chain (col. 5-6).

The '480 patent also teaches that the liposome improves antigen delivery, long term storage and provides the sustained release of given antigen at the site of administration (col. 4-5 overlapping paragraph).

Claims 41, 43 and 35 are included in this rejection as exhibiting low injection site reactogenicity (i.e. no inflammation or pathological abnormality) is inherent property of the liposomal composition comprising of multilamellar dimyristoyl phosphatidyl choline lipid.

Thus, the prior art teachings anticipate the claimed invention.

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 1, 8, 9, 12, 14, 25-27, 31, 33 and 42 are rejected under 35 U.S.C. 103 as being unpatentable over U.S. Pat. No. 5,468,494 (IDS ref) in view of U.S. Pat. No. 5,919,480 (IDS reference).

The '494 patent teaches a pharmaceutical composition comprising an amino acid sequence consisting of SEQ ID NO:7 (gastrin 17) coupled to SEQ ID NO:10 as a spacer and the resultant immunogenic peptide (SEQ ID NO:18) is coupled to diphtheria toxoid (claims 1-5, abstract, col. 1, lines 40-68), use of Nor-MDP as an adjuvant (col. 4, example 2) and administration of 2mg of immunogenic composition to rabbits (example 4).

The '494 patent does not teach the liposomal composition.

However, the '480 patent teaches that the liposome improves antigen delivery, long term storage and provides the sustained release of given antigen at the site of administration (col. 4-5 overlapping paragraph).

Therefore, one of the ordinary skill in the art would have been motivated to combine the composition taught by the '494 patent in the liposomal composition taught by the '480 patent because the liposomal composition taught by the '480 patent improves antigen delivery, long term storage and provides sustained release ('480 patent, col. 4-5 overlapping paragraph).

From the teachings of references, one of the ordinary skill in art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of the ordinary in the art at the time the invention was made, as evidenced by references, especially in the absence of evidence to the contrary.

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14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-12, 14 and 18-33 are provisionally rejected under the judicially created doctrine of double patenting over pending claims 1-21, 28 and 43 of copending application No. 11/036,690. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims encompass the injectable liposomal composition comprising hormone receptor and spacer.

16. No claims are allowable.


17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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January 11, 2006


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